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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,716	03/30/2001	David A. Edwards	2685.1003-008	7248

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/26/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/822,716

Applicant(s)

EDWARDS ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt is acknowledged of the Declaration, Fee, and Extension of Time, received by the Office on September 24, 2001, as well as the Information Disclosure Statement, received October 9, 2001.

#### ***Information Disclosure Statement***

The cited references listed on the information disclosure statement filed October 9, 2001 were not present when the application reached the examiner. The examiner printed out each of the US Patents, as well as some of the foreign patents. The entire IDS has been placed of record in the file, but only the references which are initialed on the 1449 form have been considered. The examiner kindly requests that a copy of the un-initialed references be sent with the response to this action, if applicant wishes them to be considered.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-52 are rejected under the judicially created doctrine of double patenting over claims 1-28 of U.S. Patent 5,874,064 **and** claims 1-31 of U.S. Patent RE 37,053 E **and** claims 1-28 of U.S. Patent 6,254,854 **and** claims 1-27 of U.S. Patent 5,985,309 **and** claims 1-33 of U.S. Patent 5,855,913 **and** claims 1-40 of U. S. Patent No. 6,136,295, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: each patent discussed above and the instant application claims a composition for delivery to the pulmonary system comprising a dry powder having a therapeutic agent, preferably insulin, and a carrier, wherein the composition has a tap density of less than about 0.4 g/cm<sup>3</sup>, a median geometric diameter of between about 5 and 340 microns, and an aerodynamic diameter of between about 1 and 5 microns. Additionally, the above listed patents and the instant application all claim the method for pulmonary delivery using the above mentioned composition. Although the instant application contains an additional component (the multivalent metal cation), the previous patents contain comprising language, and therefore allow for the presence of additional materials. Therefore, the subject matter of the instant claims overlaps the subject matter of the previously allowed patents.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-7, 11-17, 21-26, 28, 49, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Us Patent 6,043,214 to Jensen *et al.*. Jensen *et al.* disclose a process for producing a therapeutic powder formulation . More specifically, Jensen *et al.* teach a dry powder composition comprising insulin or an analogue or derivative thereof, an enhancer, and zinc (column 2, lines 46-48). Jensen *et al.* also teach that administration of insulin via the pulmonary route an be accomplished by either an aqueous solution or a powder preparation (column 1, lines 51-55). Jensen *et al.* also teach that the enhancer can be a phospholipid, such as lysophosphatidylcholine (column 3, lines 1-7). Jensen *et al.* teach that in a particular embodiment of the present invention the solution (which is later dried to form a dry powder) further comprises zinc, preferably in an amount corresponding to between 2 and 12 Zn atoms per insulin hexamer (column 3, lines 41-45). The reference also teaches that amino acids such as Leucine, Alanine and Valine (column 7, claims 23). Jensen *et al.* also teach that the size of the particles is between 1-5 microns (column 4, line 47). Lastly, Jensen *et al.* teach that the powder formulation obtained in their disclosure may optionally be combined with a carrier or excipient generally accepted as suitable for pulmonary administration (column 4, lines 9-12).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen *et al.*, as discussed above, and in view of the following comments.

Jensen *et al.* are discussed above as teaching a formulation for pulmonary use comprising insulin, or an analogue or derivative thereof, an enhancer, which can be phosphatidylcholine, and zinc. Jensen *et al.* do not teach the tap density of the formulation, as claimed in the instant claims. The burden is shifted to applicant to show that the composition described by Jensen *et al.* does not contain the same properties as the instantly claimed formulation. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Additionally, Jensen *et al.* do not teach the inclusion of a carboxylic acid. However, the reference does teach that the pH is adjusted. Additionally, carboxylic acids, such as citric acid, are well known pH adjusters, in both the cosmetic and pharmaceutical arts. [See the attached

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excerpt from the International Cosmetuic Ingredient Dictionary and Handbook- which lists citric acid as a well known pH adjuster.] It is the position of the examiner that citric acid is a well known component in pharmaceutical formulations. Additionally, it is known to perform a function which is specifically required by the teachings of Jensen, pH adjustment. Therefore, one of ordinary skill in the art would have bee motivated to use citric acid in the formulation of Jensen, to perform the pH adjusting function. The expected result would be a successful formulation for the pulmonary delivery of insulin. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep  
July 23, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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